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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,039	06/06/2001	Lawrence H. Mainwaring	104222	7602

7590 12/17/2003
Oliff & Berridge PLC
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EXAMINER

BUI, LUAN KIM

ART UNIT PAPER NUMBER

3728

DATE MAILED: 12/17/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/874,039

Applicant(s)

MAINWARING ET AL.

Examiner

Luan K Bui

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 7-29, 31-50, 53, 54, 57, 58- is/are rejected.
- 7) ☒ Claim(s) 6, 30, 51, 52, 55 and 56 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-4, 10-20, 31-48, 57 and 58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, the phrase “the at least one applicator” lacks proper antecedent basis.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-4 and 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Hickey (6,412,639). Hickey discloses a single-use applicator assembly (100) for dispensing and applying a polymerizable monomeric medical adhesive material comprising a base portion (115) having at least one sealed compartment, a polymerizable monomeric adhesive material (150) contained in the at least one compartment and an applicator (146) at least partially disposed in the at least one compartment such that a tip of the applicator is proximate the polymerizable

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monomeric adhesive material. As to claims 3 and 4, Hickey discloses the medical adhesive material comprises a polymerizable 1,1-disubstituted ethylene monomer formulation such as an alpha-cyanoacrylate. As to claims 18 and 19, Hickey discloses the medical adhesive material is pre-sterilized prior packaging (column 7, lines 65-67).

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-5, 7-10, 12-29, 31, 33-37, 39, 40, 43, 45, 46, 49, 50, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Discko, Jr. (5, 660,273) in view of Leung (5,928,611) and Hickey (6,412,639). Discko, Jr. discloses a single-use applicator assembly for dispensing and applying a medicament or material comprising a base portion (110, 210) having a first sealed compartment (112, 212) containing the medicament (124, 224) and a second sealed compartment (114, 214) containing an applicator with tip (120, 121, 220, 221) and a cover (126, 226). Discko, Jr. further discloses the applicator assembly is destructively unsealed by removal of the applicator (see abstract and Figure 15). Discko, Jr. fails to show the medicament being a polymerizable monomeric adhesive material. Leung shows a single-use applicator assembly (100) comprising an applicator container (200) having a compartment for holding polymerizable and/or cross-linkable material (300) and an applicator tip (500) attached to the container. The applicator tip containing a polymerization and/or cross-linkable initiator (Figure 3). Hickey

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discloses a single-use applicator assembly (140) for dispensing and applying a polymerizable monomeric medical adhesive material comprising a container (144) having a compartment containing a polymerizable monomeric adhesive material (150) and an applicator with tip (146) attached to the container (Figure 16). The medical adhesive material comprises a polymerizable 1,1-disubstituted ethylene monomer formulation such as an alpha-cyanoacrylate. Hickey further discloses the medical adhesive material is pre-sterilized prior packaging (column 7, lines 65-67) and the tip may have on or in it a polymerization initiator or rate modifier (column 10, lines 1-17). It would have been obvious to one having ordinary skill in the art in view of Leung and Hickey to modify the assembly of Discko, Jr. so the medicament comprises a polymerizable monomeric adhesive material to allow the assembly for holding various medicament or material such as a polymerizable monomeric adhesive material. As to claim 26, Leung shows The applicator tip containing a polymerization and/or cross-linkable initiator and Hickey discloses the tip may have on or in it a polymerization initiator or rate modifier which is considered equivalent to the medicament as claimed. Claims 45, 46, 49, 50, 53 and 54 are drawn to the obvious method of using the assembly of Discko, Jr. as modified.

Allowable Subject Matter

4. Claims 6, 30, 51, 52, 55 and 56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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5. Claims 11, 32, 38, 41, 42, 44, 47, 48, 57 and 58 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments


Applicant's arguments with respect to all pending claims have been considered but are deemed to be moot in view of the new grounds of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Luan K. Bui whose telephone number is (703) 305-5861. If in receiving this Office Action, it is apparent to Applicant that certain documents are missing from the record for example copies of references cited, form PTO-1449, form PTO-892, etc., requests for copies of such papers should be directed to TC 3700 Customer Service at (703) 306-5648.

Any inquiry of a general nature or relating to the status of this application should be directed to the Customer Service whose telephone number is (703) 872-9301. Facsimile correspondence for this application should be sent to (703) 872-9302 for Formal papers and (703) 872-9303 for After Final communications.

lkb
December 11, 2003


Luan K. Bui
Primary Examiner